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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/975,607	10/11/2001	Kathryn S.E. Cheah	0467/57114-B/RDK/NML	9933

7590 08/13/2003
Robert D. Katz
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1185 Avenue of the Americas
New York, NY 10036

EXAMINER

PARAS JR, PETER

ART UNIT	PAPER NUMBER
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1632

9

DATE MAILED: 08/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/975,607

Applicant(s)

CHEAH ET AL.

Examiner

Peter Paras, Jr.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☒ Interview Summary (PTO-413) Paper No(s). 10.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Upon further consideration, the previous restriction requirement mailed on 4/23/03 has been vacated. A new restriction requirement is presented below.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-5, drawn to a polynucleotide encoding a collagen X and method of producing a polypeptide, classified in classes 536 and e435, subclasses 23.1 and 70.1.
- II. Claims 6-13, drawn to a collagen X polypeptide, and methods of treatment using the same polypeptide, classified in classes 530, and 424, subclasses 350, and 184.1.
- III. Claims 10-14, drawn to methods of treatment using a nucleic acid molecule encoding a collagen X, classified in class 514, subclass 44.
- IV. Claims 15-20, drawn to a transgenic animal comprising a polynucleotide encoding a collagen X, and methods of using the same transgenic animal, classified in class 800, subclass 13.

It is noted that claim 14 appears to be inadvertently dependent from claim 9. For the purposes of the instant restriction requirement claim 14 will be grouped only with the nucleic acid treatment claims.

Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper between Groups I, II, III, and IV because their methods appear to constitute patentably distinct inventions, each with a distinct purpose and further comprising distinct methodologies and using different products. For example, the method of Group I requires the use of a nucleic acid molecule to produce a polypeptide, the methods of Group II require the use of a polypeptide for treatment of bone disorders, the treatment methods of Group III require the use of subjects having bone disorders and administration of a nucleic acid molecule encoding a collagen X to the same, and the method of Group IV requires the use of a transgenic animal. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, different classification, and separate search requirement, restriction for examination purposes as indicated is proper.

It is noted that the Group II claims comprise methods of treating different disorders by administering a collagen X polypeptide. If the Group II claims are elected, further restriction to a particular disorder may be required as follows:

Claims 10-11 and 13 are generic to a plurality of disclosed patentably distinct species of treatment methods for different bone disorders comprising administration of a collagen X polypeptide:

A. dwarfism

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B. low bone mass

C. bone fractures

Patentably distinct methods for treating bone disorders are encompassed by the claim. A specific member of an elected species of bone disorder should be elected.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, from one of groups A-C, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

It is noted that the Group III claims comprise methods of treating different disorders by administering a nucleic acid molecule encoding a collagen X polypeptide. If the Group III claims are elected, further restriction may be required.

Claims 10-11 and 13 are generic to a plurality of disclosed patentably distinct species of treatment methods for different bone disorders comprising administration of a polynucleotide encoding collagen X:

A. dwarfism

B. low bone mass

C. bone fractures

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Patentably distinct methods for treating bone disorders are encompassed by the claim. A specific member of an elected species of bone disorder should be elected.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, from one of groups A-C, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Peter Paras, Jr., whose telephone number is 703-308-8340. The examiner can normally be reached Monday-Friday from 8:30 to 4:30 (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at 703-305-4051. Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703) 308-4242 and (703) 305-3014.

Inquiries of a general nature or relating to the status of the application should be directed to Dianiece Jacobs whose telephone number is (703) 305-3388.

Peter Paras, Jr.

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PETER PARAS
PATENT EXAMINER